UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA; and

THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, and TEXAS; and

THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and

THE DISTRICT OF COLUMBIA;

ex rel. JANE DOE,

Plaintiffs,

v.

VERTEX PHARMACEUTICALS INC. and

GLAXOSMITHKLINE

Defendants.

CIVIL ACTION NO.

CV 07 4058

FILED IN CAMERA and UNDER SEAL

COGAN, J.

POLLAK, M.J.

FALSE CLAIMS ACT *QUI TAM* COMPLAINT

INTRODUCTORY STATEMENT

1. This is an action brought on behalf of the United States of America by Plaintiff JANE DOE (hereafter referred to as "Relator") against Defendants pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the above-named States under their

respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action"). Pursuant to 31 U.S.C. § 3730(b)(2), and comparable provisions in the State FCAs, this action is brought *in camera* and under seal.

2. The Relator in this case is a former employee of Defendant Vertex Pharmaceuticals Inc. The allegations of this Complaint arise from the Relator's first-hand knowledge of the unlawful practices of the Defendants with respect to the human immunodeficiency virus ("HIV") protease inhibitor Lexiva.

3. The Defendants in this case have violated several laws, including without limitation, the Federal and State FCAs, the Medicare and Medicaid Anti-Kickback Act, and the Federal Food, Drug, and Cosmetic Act by engaging in numerous unlawful activities in their marketing and other activities in connection with Agenerase and Lexiva from at least October 2000 through the present and continuing. The Defendants' unlawful activities include, without limitation:

(i) the "off-label" marketing of Lexiva for unapproved dosing regimens in order to cause the drug(s) to be prescribed instead of competing drugs;

(ii) the off-label marketing of Agenerase for use in combination with other drugs, not indicated by the label;

(iii) the payment of kickbacks to physicians willing to promote Lexiva in presentations to other doctors;

(iv) the "seeding" of medical studies designed to justify commercial interests; and

(v) the marketing of experimental drugs not approved by the FDA.

4. The purpose of these unlawful activities is to gain market share for Agenerase and

Lexiva and potentially for Defendants' pipeline of HIV and Hepatitis C drugs and to increase reimbursement for Agenerase and Lexiva from governmental (and private) health insurance programs. Defendants' actions and omissions have caused improper and illegal billings to the federal government and to the state governments named herein. The off-label dosing of Lexiva with a reduced supplement of Ritonavir can lead to loss of viral suppression and may cause the patient to develop resistance to the entire class of protease inhibitors. On information and belief, the damages caused to Government Health Care Programs as a result of Defendants' unlawful activities exceeds $300 million in single damages. The foregoing unlawful practices are detailed in the pages below, and also in Relator's Disclosure served on (or otherwise made available to) the federal and state Plaintiffs in this matter.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has supplemental jurisdiction over the State FCA claims pursuant to 28 U.S.C. § 1367.

6. Venue is appropriate as to the Defendants in that the Defendants transact business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) & (c), and 31 U.S.C. § 3732(a).

7. To Relator's knowledge, jurisdiction over this action is not barred by 31 U.S.C. § 3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and Relator is an "original source" of the information upon which these allegations are based.

THE PARTIES

8. Relator Jane Doe is a citizen of the United States of America. Relator has provided, and/or will otherwise make available, appropriate Disclosures to the United States and to the Plaintiff States pursuant to the Federal and State FCAs.

9. Defendant Vertex Pharmaceuticals Incorporated ("Vertex") is a publicly-traded biotechnology company listed on NASDAQ (symbol: VRTX). The corporation is registered in the Commonwealth of Massachusetts and has its principal business address at 130 Waverly Street, Cambridge, Massachusetts 02139. Vertex conducts business throughout the United States and has research facilities in San Diego, California and Oxford, England. Vertex is engaged in the search for, and development of, small molecule drugs for the treatment of viral diseases, inflammation, autoimmune diseases, cancer, pain and bacterial infection. Vertex co-discovered the HIV protease inhibitors Agenerase and its replacement Lexiva with GlaxoSmithKline.

10. Defendant GlaxoSmithKline ("GSK") is the second largest pharmaceutical corporation worldwide. GSK's stock is publicly-traded on both the New York and London stock exchanges (symbol: GSK). The company employs more than 100,000 people and has its headquarters in Brentford, Middlesex, England and maintains US headquarters at Franklin Plaza, Philadelphia, Pennsylvania. In 2003 GSK signed a corporate integrity agreement and paid $88 million in a civil fine for overcharging Medicaid for the antidepressant Paxil. GSK enjoys worldwide marketing rights for Lexiva and pays royalties to Vertex.

FEDERAL AND STATE LAWS

Government Health Insurance Programs

11. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, (hereinafter "Medicare"), is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

12 The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

13. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers

to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

14. The federal government, including through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

15. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries.

16. The Ryan White Comprehensive AIDS Resources Emergency ("CARE") Act (the "Ryan White Act") was passed in August of 1990. It is the United States' largest federally funded program for people living with HIV/AIDS. The act sought funding to improve availability of care for low-income, uninsured and under-insured victims of AIDS and their families. Unlike Medicare or Medicaid, Ryan White programs are "payer of last resort," funding treatment when no other resources are available.

17. In 1991, the first year funds were appropriated, around $220 million was spent; by the early 2000s, this number had almost increased to over $2 billion per annum.

The Ryan White Care Act was reauthorized in 1996, 2000 and 2006. The program provides some level of care for around 500,000 people a year and, in 2004, provided funds to 2,567 organizations. The Ryan White programs also fund local and State primary medical care providers, support services, healthcare provider training programs, and provide technical assistance to such organizations.

18. In fiscal year 2005, federal funding for the Ryan White Care Act was $2.1 billion. As of 2005, roughly one third of this money went to the AIDS Drug Assistance Program ("ADAP"). The primary activity of ADAP is providing FDA-approved prescription medication. In 2006, the Ryan White Act was reauthorized for three more years, ending on September 30, 2009 with a funding level of $2.1 billion per annum.

19. Together these programs, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

20. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, *et seq.*, prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) and (d). An approved drug may be prescribed by doctors for uses and in doses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off-label" uses or unapproved doses. 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, or a new unapproved dose, it must apply to the FDA (or an exemption therefrom must be obtained) and any promotional materials

concerning such applications must meet strict statutory and regulatory requirements. *See* 21 U.S.C. §§ 360aaa, *et seq*.

21. Whether a drug is FDA-approved for a particular use, or at a particular dose, determines whether a prescription of the drug is reimbursed under many, if not all, Government Health Insurance Programs, including Medicaid. Reimbursement under Medicaid and these other programs is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. §1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* §1396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in a specified drug compendia. *Id.* §1396r-8(k)(6). Thus, unless a particular off-label dose or use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid. There is a single exception: in certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an "off-label" application where the individual State has determined, *inter alia*, that the drug is essential to the health of beneficiaries. 42 U.S.C. §1396r8(a)(3).

22. The FFDCA provides criminal penalties for the dissemination of written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the FDA approved labeling of the drug, if that written information fails to conform to the law's requirements. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa. One of

those requirements is that a manufacturer may disseminate written information on a new use of a drug only if the information is about a clinical investigation with respect to the drug and is contained in an article published in a scientific or medical journal, which is peer-reviewed by experts, or in a reference publication. 21 U.S.C. §360aaa-1 states in part:

> (a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –
>
> (1) is in the form of an unabridged –
>
> (A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness
> of the drug or device involved, which were published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which
> is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or
>
> (B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such
> a clinical investigation . . . .

The Federal and State False Claims Acts

23. The Federal FCA, 31 U.S.C. § 3729(a)(1), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

24. The Federal FCA, 31 U.S.C. § 3729(a)(2), makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

25. The Federal FCA, 31 U.S.C. § 3729(a)(3), makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

26. The Federal FCA, 31 U.S.C. § 3729(a)(7), makes it illegal for any person to "knowingly" make, use or cause to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

27. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government

will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

28. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code §§ 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*, Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, § 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, §§ 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), 2007 New York Laws 58, section 39, Art. XIII, §189, *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.* These State False Claims Acts apply, *inter alia,* to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing, *inter alia*, a Relator's right to claim a share of the State's

recovery.

The Medicare and Medicaid Anti-Kickback Act

29. The Medicare and Medicaid Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b (b), makes it illegal to offer, pay, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services. Many States have similar anti-kickback laws governing their respective Medicaid programs.

OIG Guidelines on Education and Research Funding

30. As noted above, under the Anti-Kickback Act, it is illegal to, *inter alia*, offer or pay, receive or solicit any remuneration, kickback, bribe, or rebate, in cash or in kind, directly or indirectly, overtly or covertly, to induce such person to order, arrange for or recommend the purchasing or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program. In May 2003, the Inspector General of HHS published further guidance on marketing practices which may constitute kickbacks known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the

"OIG Guidelines"). The OIG Guidelines address the conflicts which may arise when a pharmaceutical manufacturer provides educational or research funding to "entities in a position to make or influence referrals." As a general rule, suc grants should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden *quid pro quo* relationship.:

> "Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program." *Id.* § II (b)(2)

31. The OIG has not defined the term "unrestricted educational grant", however, 5 C.F.R. 5501.109 (b)(12), which regulates HHS employees, defines the term as follows:

> "Unrestricted educational grant means funds received by or available to an educational activity provider from another source that are granted without stipulated conditions for their use other than the limitation that the funds shall be used to advance an educational program of the grant recipient. For purposes of this section, an educational grant shall not be considered unrestricted if the funding source for a continuing professional education program directly or indirectly:
>
> (i) Selects or recommends the moderators, speakers, or presenters at the sponsored event;
> (ii) Independently provides additional funding to the moderators, speakers, or presenters in connection with the educational activity;
> (iii) Determines or recommends the audience composition;
> (iv) Specifies or recommends the topics to be addressed; or
> (v) Controls or recommends the planning, content, or implementation of the program in a manner inconsistent with guidelines established by a relevant professional association or accrediting organization that are designed to ensure that such activities are accurate, balanced, educational, free from commercial bias, nonpromotional, and independent of the influence of the funding source."

Because of the obvious potential for a conflict of interest when a pharmaceutical manufacturer makes an educational grant to a potential customer, or one in a position to

influence a potential customer, the OIG Guidelines make the following recommendation:

> "To reduce the risk that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions." *Id.*

FACTS AND ALLEGATIONS

THE RELATOR: JANE DOE

32. Relator brings this *Qui Tam* action based upon direct and unique information obtained as a result of her employment at Vertex. Relator's identity and employment information is provided in the Disclosure Statement being produced to the United States and made available to the Plaintiff States pursuant to the Federal and State FCA. Through her employment with Vertex she has acquired direct, unique and first hand information about the sales, marketing, clinical affairs and regulatory aspects of the Defendants' commercial business.

AGNERASE (Amprenavir) and LEXIVA (Fosamprenavir calcium)

33. Agenerase (Amprenavir) is a drug of the protease inhibitor ("PI") class indicated for the treatment of HIV infection in adults and children and was first approved by the FDA on April 15, 1999. Agenerase is approved only in combination with other anti-HIV medicines. When Agenerase is co-administered with Ritonavir (another PI), the approved dosing regimens are: Agenerase 1,200 mg with Ritonavir 200 mg, once daily or Agenerase 600 mg with Ritonavir 100mg twice daily. Until recently, Agenerase was manufactured in two capsules of either 50 or 150 mg or in liquid form. Since the development of the *prodrug* Lexiva, GSK has ceased production of the 150 mg capsule and Lexiva has taken over from Agenerase in the marketplace.

34. Lexiva is also a drug of the protease inhibitor ("PI") class indicated for the

treatment of HIV infection in adults and children. Lexiva was first approved by the FDA October 20, 2003. As a *prodrug* of Agenerase, Lexiva is inactive at the time of administration then is converted by the body into the active drug Agenerase. In adults, Lexiva is approved at a daily dose of 1400 mg in conjunction with 200 mg of Ritonavir. This combination may be taken once daily (1400 mg Lexiva with 200mg Ritonavir) or twice daily (700 mg Lexiva with 100mg). However, Lexiva is only indicated for use on its own, i.e. without Ritonavir, in "therapy-naïve" adults. "Therapy-naïve" patients are those HIV patients who are new to HIV therapy. Such therapy-naïve patients may, *but need not be*, treated with Lexiva alone. However, where Lexiva is prescribed in conjunction with Ritonavir, then the patient must take the full 200 mg supplement on a daily basis, even if the patient is therapy-naive.

35. The Department of Health and Human Services (DHHS) and the International AIDS Society (IAS) have both produced guidelines on how best to treat HIV patients. Both sets of guidelines recommend a Ritonavir-boosted PI as the preferred *first* line regimen for a patient *initiating* PI-based therapy. That is to say that, even therapy-naive patients are advised to take Lexiva with Ritonavir, in which case they must take the full 200mg of Ritonavir on a daily basis. Any Lexiva prescriptions written which allow the patient to take less than 200mg Ritonavir (most typically 100mg) are "off label" prescriptions, whether the recipient is new to HIV therapy or not.

RITONAVIR (Norvir)

36. Ritonavir is a protease inhibitor manufactured by Abbott Laboratories and first approved on March 1, 1996. In its early days, Ritonavir was used primarily as a monotherapy and patients took daily doses of 1200 mg. Today, however, the drug is used

in increasingly small amounts to "boost" other protease inhibitors such as Lexiva. This reduction in demand for Ritonavir led to a controversial move in 2004 by Abbott to quadruple the drug's price. Ritonavir is notorious for its unpleasant side effects which include nausea, vomiting, gas, and diarrhea. It is estimated that the side effects cause one third of patients to stop taking the drug. However, the side effects are much reduced when the drug is used as a booster to other protease inhibitors and, as a general rule, the side effects decrease as the dose of Ritonavir decreases. Accordingly, a protease inhibitor which requires less Ritonavir is generally more tolerable and therefore more popular; and, given the quadrupling of the price of Ritonavir, cheaper.

LEXIVA's COMPETITIVE DISADVANTAGE

37. This requirement that all Lexiva prescriptions written with Ritonavir are to be boosted with the full 200mg, puts Lexiva at a competitive disadvantage with other PI's, for example Bristol Myers Squibb's Reyataz (Atazanavir), which requires only 100mg of Ritonavir. As Mari Brill, the Vertex MSL in San Diego, noted in her field report of May 19, 2006 : "physicians prefer regimens with the least amount of rtv." Dr. Bisher Akil of Los Angeles was noted as commenting that "the concept of 1400/100 instead of 1400/200 is 'very attractive' and will further help FPV [Lexiva] compete against ATV [Reyataz] for first or second PI" (Field Report of Chris Barnes January 26, 2006). As the attendees at one advisory board in New York stated "They [the attendees] said that GSK and Vertex MUST pursue 1400/100 in order to secure a place as the first boosted PI" (emphasis in original) (Field report of Jill Dacierno June 24, 2005) The Vertex MSL's and GSK sales reps heard this objection time after time to the point where it became a cliché statement of the obvious.

38. Consequently, Defendants' strategy was to persuade doctors that, despite the label, Lexiva was just as safe and effective in a single daily dose with just 100mg of Ritonavir. This approach enabled Lexiva to compete head-to-head with rivals such Reyataz and put Lexiva ahead of other PI's requiring a booster of 200 mg of Ritonavir.

KALETA PARA

VX 385 & VX 950

39. VX 385 (Brecanavir) is a protease inhibitor which was under development by Defendants. The drug reached Phase 2 clinical trials but was abandoned by GSK due to adverse events. GSK notified Vertex that it would no longer continue to sponsor the development of VX 385 on December 15, 2006.

40. VX 950 (Telapravir) is an oral hepatitis C ("HPC") protease inhibitor currently under development by Vertex in collaboration with Janssen. The FDA has granted "fast track" designation to VX 950 and Vertex is conducting three major Phase 2 clinical trails (the "PROVE" trials). Under the agreement with Janssen, Vertex has retained the exclusive commercial rights to VX 950 in North America. In their 2006 Annual Report, Vertex announced that it intends to "commit significant personnel and financial resources" to build a marketing organization and a direct sales force for VX950.

GSK's RELATIONSHIP WITH VERTEX

41. In 1993, Vertex entered into a co-operation agreement with GSK covering the development of HIV inhibitors generally, including specifically Agenerase, Lexiva and VX 385. GSK pays Vertex royalties based on the sales of all HIV PI's covered by the agreement. Under the terms of their agreement, GSK has a right to terminate its collaboration with Vertex on twelve months' notice.

42. GSK enjoys worldwide marketing rights for Lexiva and pays royalties. Vertex has no official responsibility for marketing and sales and does not currently maintain a sales force. In their 2006 annual report, Vertex stated that "We have no experience as a company in sales and marketing." Nevetheless, through the unlawful activites descibed in this complaint, Vertex operated much like a sales and marketing arm of GSK taking feedback from the marketplace, seeding off-label studies to fill "data gaps" and spinning the emerging data. The chief aim of these off label activities was to promote Lexiva with a reduced dose of Ritonavir to overcome its competitive disadvantage (despite the fact that there is no significant scientific support for this strategy). This off label promotion also runs the risk of causing patients to become resistant to *all* protease inhibitors and reverse transcriptase inhibitors. Defendants also sought to convey, incorrectly, that Agenerase and Lexiva were particularly effective when taken in combination with Abbott's Kaletra (Lopinavir with Ritonavir).

MEDICAL SCIENCE LIAISONS

43. The arrangement between GSK and Vertex is such that GSK is responsible for sales and marketing of the drug, while Vertex manages a small, elite team of eight or so Medical Science Liaisons ("MSL's"). Inside Vertex the MSL's were referred to as "Influence Managers" and each MSL participates in extensive training on the art of "influence management." MSL's are instructed to "focus on activities that have an impact nationally" to which end they use "advisory board" meetings, mini "investigator initiated studies" and publications to attract and reward key opinion leaders or "KOL's." Vertex selects only the most influential doctors as their targets, thereby leveraging the influence each MSL might have nationwide. The echelon of doctors

called upon by the Vertex MSL is made up of no more than 100 physicians nationwide. By favoring the most influential doctors with lucrative speaking engagements and miniature studies, the company turned many of these doctors into *de facto* sales reps for Vertex.

44. Vertex holds regular, regional "advisory boards" ostensibly to solicit the opinion of Key Opinion Leaders. In reality, these meetings provide a convenient forum for the off-label promotion of Lexiva with the reduced dose of Ritonavir. The "ad boards" involve a meal, whether lunch or dinner, and the payment of an attendance fee of $1000 to $1500 plus expenses. Speakers, who receive $1500 to $3000 per meeting, are groomed to convey the reduced Ritonavir dosing strategy (1400mg Lexiva with 100 mg Ritonavir once daily) and promote drugs not yet approved by the FDA, such as VX 385. Doctors who have received money from Vertex to produce Lexiva-friendly studies were then paid again to present results at ad boards, medical education programs and during one-to-one meetings called "peer-to-peers" with other doctors.

45. MSL's are judged and rewarded by their ability to promote Lexiva off-label and "seed" Lexiva friendly studies. At the beginning of 2005, all MSL's were informed by group management (Tyke White and Shahin Gharakhanian) that their ratings and bonuses that year would be directly tied to the number of Lexiva-related studies and or publications that they managed to engineer. Consequently in the first quarter of 2005, there were a flood of study proposals stage managed by the MSL's, resulting in a stream of data throughout the remainder of the year. In 2005, sales of Lexiva jumped 50% over the previous year. While Vertex strove ever to increase the number of these converted KOL's, there were never enough of them, as Tyke White, national MSL manager,

lamented in an email of September 13, 2006 "we are limited in the number of low-dose speakers."

46. Those MSL's who made little progress in getting studies produced or who failed to "groom" their speakers were disfavored. For example, Mari Brill (MSL for San Diego) was to prepare a speaker, Courtney Fletcher Pharm D., for a Vertex-sponsored CME talk. When Tyke White and Bruce Teris reviewed the slides for the event, they made extensive changes and later criticized Ms. Brill, in front of all the MSL's for failing to exert sufficient influence over the speaker in the first place. This issue was again raised in Ms. Brill's annual review to her detriment.

VERTEX MEDICAL INFORMATION SYSTEM AND FIELD REPORTS

47. Vertex's MSL's would write up their interactions with doctors in a database known as VMIS ("Vertex Medical Information System"). The VMIS has a drop-down menu which allows the creation of "Field Reports" which are required once or twice a month. The VMIS provides an insight into Vertex's ideal MSL. At one time, Relator and all other MSL's had complete access to the VMIS for all MSL's. However, in mid 2006, all reports prior to that year were no longer accessible, if they continued to exist at all.

48. Relator found that many of the missing VMIS entries, were still accessible in summary form in the Field Reports. Relator was able to access Field Reports going back to 2004, but no earlier. Relator is also aware that certain emails have been selectively deleted from the MSL-accessible database sometime in 2006. The email string (between Tyke White, Bruce Teris and Courtney Fletcher) regarding Courtney Fletcher's talk for Mari Brill is one of a number of emails which disappeared (See

paragraph 46).

DEFENDANTS SEEDED LEXIVA STUDIES

49. Defendants pursuit of their reduced-Ritonavir dosing strategy has all along been handicapped by the absence of any supporting clinical data. Chris Barnes, MSL in Los Angeles reported "the 100mg data has impact, but KOL's would like to see more clinical data and to see studies powered to show non-inferiority against standard of care regimens such as Reyataz." (Field Report of Chris Barnes March 20, 2006) This sentiment is repeated in the Field Report of Jill Dacierno dated October 31, 2005 "1400/100 … Many providers are doing this already based on the PK [pharmacokinetic] data and word of mouth among treaters. The clinical data is much needed." Again, Jill Dacierno, reported that a Dr. Martin Markowitz "definitely thinks that Lexiva/r 1400/100 QD will be a winner if the large clinical trial can prove that it's a viable option." (Field Report of November 28, 2005) Relator and other MSL's have consistently noted comments from doctors to the effect that physicians need to see more data before adopting an alternative dosing strategy.

50. The team at Vertex which sought to remedy these insufficiencies was the grants committee known as "HIVCOT" (HIV commercial operations team). In Relator's experience HIVCOT never approved a single unsolicited grant, but instead originated ideas for studies to bridge "data gaps" and then had their MSL's approach likely thought leaders to see how much the proposal would cost.

51. Because of the obvious potential for a conflict of interest when a pharmaceutical manufacturer makes an educational grant to a potential customer, or one in a position to influence a potential customer, the OIG Guidelines make the following

recommendation:

> "To reduce the risk that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions."

"OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines").

52. While the OIG recomends that grants and marketing be separate to prevent research money being used to influence researchers, at Vertex, the two programs were combined for this very reason. The HIVCOT committee was made up of Shahin Gharakhanian, (now Vice-President of Medical Affairs) Tyke White (national MSL Director), and Bruce Teris (Senior Marketing Manager), and was more like a promotional think tank: HIVCOT would decide what "studies" were needed to promote Lexiva and the MSL would solicit doctors to undertake the research. Once a reseracher was identified, the MSL, not the doctor, would write a proposal to Tyke White asking for the sum of money agreed upon and a check would be written directly to the doctor. If questioned on the legailty of these prcatices, Tyke White would respond that "We are a small company. We fly under the radar."

53. As a general rule, educational grants should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden *quid pro quo* relationship:

> "Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program." OIG Guidelines § II (b)(2)

Defendants positively strove to develop such forbidden quid pro quo relationships and succeeded in the following three examples: Dr. Brian Boyle; Dr. David Parks; and

Dr. Ricky Hsu.

BRIAN BOYLE, VIRALED AND THE PI COMPARISON DECK

54. Brian Boyle is a New York doctor on the faculty of the Weill Cornell Medical School. Dr. Boyle, who also holds a *juris doctorate* from Notre Dame Law School, no longer practices medicine, but is regarded as a thought leader in the field of HIV/AIDS. Dr. Boyle has a close and longstanding relationship with Vertex and GSK. During the years 2003 to 2006, he chaired virtually all of the Vertex Advisory Boards all over the country and received payments from both Vertex and GSK. On information and belief, in 2003 Vertex paid Dr. Boyle, through his corporation ViralEd, $40,000 to author a comparison of protease inhibitors, known as the "PI comparison deck." This document was ostensibly an objective professional's assessment of the numerous inhibitors on the market. However Dr. Boyle allowed Vertex to influence his assessment of Lexiva and effectively promote it ahead of other protease inhibitors. According to the field report of Jill Dacierno of August 26, 2005 she was "working with Brian updating the PI Comparison Deck. He was receptive to the changes that I requested." The PI Comparison Deck has been an ongoing source of work for Dr. Boyle and it has brought fringe benefits such as international travel. According to Dacierno's field report of August 26, 2005 "Brian is more than happy to go to France to give talks on the PI comparison deck." Since the project was first completed, Dr. Boyle has been paid to update the deck at least eighteen times.

55. Dr. Boyle has used the ghost written PI Comparison Deck in the course of teaching a CME course at the University of Florida. In Dacierno's field report of January 31, 2006, she noted that "He used the PI comparison deck that was originally

commissioned by VRTX. The bottom line in the PK section is that FPV [Lexiva] is a clear winner!" (emphasis added) In this way, Vertex has unawfully positioned Lexiva as the optimal medical choice for the treatment of HIV. Ironically, Dr. Boyle has also produced a PI comparison deck for Bristol Myers Squibb and, on information and belief, that deck is authored so as to position Reyataz as the optimum PI. In or about 2003, Dr. Boyle also put together an efficacy comparison of all antiretroviral drugs on the market. This "study" was initiated by Shahin Gharakhanian (Sr. Medical Director Vertex) and was presented at a European HIV conference. In addition to being paid for the "meta analysis", Dr. Boyle was paid to present this analysis at numerous Vertex advisory boards and medical education meetings.

56. Dr. Boyle has trained Vertex speakers. For example, he attended a talk given by pharmacist Andy Luber and met with Luber afterwards to give his feedback. According to the January, 2006, Field Report of Jill Dacierno, the talk was a success because "in a balanced way, Andy was able to get across all of fosamprenavir's strongest attributes." Dacierno also noted that, according to Dr. Boyle, before Luber's talk the audience were not "taking the ATV/ARA interactions seriously." In other words, Luber persuaded the audience that Lexiva was a better choice than Reyataz if the patient was also taking an acid reducing agent. As far as Relator is aware, Dr. Boyle continues to work with Vertex; indeed, earlier this year he was engaged to train new MSL's.

THE PARKS STUDY

57. The Parks study came about as a result of a HIVCOT "brain storming" session. Relator recalls that just after Lexiva received FDA approval in 2003, all the MSL's, Tyke White, Bruce Teris and Shahin Gharakhanian met at Vertex's office in

Cambridge, Massachusetts to discuss data gaps and where to seed the "investigator initiated studies." Both Vertex and GSK contrived such studies, for example, according to the "GSK Interactions" entry in the field report of Jill Dacierno dated November 28, 2005, "The [GSK] collaborative studies group is making a strong push to increase the number of investigator initiated trials… The director is coming to New York next week to meet with several physicians and walk through their data gaps."

58. Jane Musser, MSL and West Coast team leader noted in her field report of June 2005 that Dr. Nicholas Bellos "is using a lot of Lexiva QD at the 1400/100 dose. He recently spoke on this for GSK in San Jose. I suggested we pull together the charts of the patients he has on this dose and write it up. He was interested in this idea. He is speaking a lot for GSK and he is a fan of QD." Following the HIVCOT meeting in Cambridge, Chris Barnes, MSL, approached a Dr. David Parks of St. Louis, Missouri with a proposal to investigate the compatibility of Lexiva and Tenofovir, a reverse transcriptase inhibitor, marketed by Gilead Sciences. The study ultimately showed that there was no adverse interaction between the drugs. Vertex worked with Dr. Parks in producing a clinical article, a poster presented at EACS (European AIDS Clinical Society), and a second Poster presented at an HIV/AIDS conference in Rio, Brazil. The Parks data also formed the subject matter for innumerable off-label discussions with other doctors.

59. In his field report of October 14, 2005, Chris Barnes noted that Dr. Parks "sent a rough draft of the poster, although he hasn't reviewed it himself. Copies sent to Tyke [Vertex], Shahin [Vertex] and Ed Acosta for comments." The following month, MSL Barnes was able to report that he referenced the Parks Data with four doctors: Drs.

Wolfe; Bhatti; Mills; and Farthing. In his December field report, Barnes noted that the Parks data was used at a GSK dinner with Dr. Farthing and Andy Luber. The data was also presented at an Advisory Board meeting in Los Angeles on November 28, 2006.

60. Barnes has noted other proposed studies in his field reports: in May 2006 he recorded that he had "collaborated with Judith Currier as well as Naomi Givens and Cindy Garris (GSK) on creating a last-minute abstract of Lexiva gender differences Project to ICAAC [Interscience Conference on Antimicrobial Agents and Chemotherapy]." In his next field report he commented that he was "working in conjunction with GSK, Vertex and Dr. Currier to create review and approve the Poster." In his July 2006 field report, Barnes noted that he had "Worked closely with Jane Musser, Cecile LeCamus, Mari Brill, Shain Gharakhanina, HIVcot Team, Cindy Garris and Naomi Givens (GSK) in achieving submission of Ruane abstract to the Lipo workshop". However, it was the Parks data which won Barnes Vertex's high praise, after which he was invited to join the HIVCOT team and began to be regarded as "high flier."

61. The Parks data was finally published in the June 2007 edition of the Official Journal of the International AIDS Society. ("Pharmacokinetics of once-daily tenofovir, emtricitabine, Ritonavir and fosamprenavir [Lexiva] in HIV-infected subjects" Parks, David A; Jennnings, Harold C., Taylor, Christopher W. and Acosta, Edward P. AIDS. 21(10): 1373-1375, June 2007) On information and belief, when Chris Barnes found out that the article had finally been published he sent an email around Vertex taking credit for the study.

THE HSU STUDY

62. This study, according to the Field Report of Jill Dacierno of March 3,

2006 "started with a discussion in Bruce's [Teris] office on September 16th [2005], [and] led to the important interim satisfaction of a critical data gap." The "data gap" in question was the perennial lack of evidence regarding the efficacy of the off-label reduced-Ritonavir daily dosing strategy. At the time GSK had been conducting a large clinical trial to test the efficacy and safety of the 1400/100 regimen, but the results were not expected for some time. Jane Musser reported that doctors at a Houston Advisory Board meeting in March 2006, prefer the reduced-Ritonavir daily dose and "asked why fAPV [Lexiva] was not approved at 100mg qd originally." Vertex sought to fill this gap by getting something done quickly and to order.

63. A month after the marketing meeting, Jill Dacierno approached Dr. Ricky Hsu, a Manhattan doctor and sometime Vertex consultant, to perform a "study" aimed at proving that Lexiva was just as effective using just 100 mg of Ritonavir. Dr. Hsu had proven his reliability to Vertex in the past. As Jill Dacierno, New York MSL, Medical Education Coordinator and most recently Associate Director, East Coast MSL's, put it "You did such a nice job with the 1200/200 years ago, that everyone at Vertex has a lot of faith in your work." On information and belief, this is reference to research used to gain FDA approval for Agenerase.

64. Ms. Dacierno also knew from experience that Dr. Hsu was amenable to editorial input from Vertex. Two years previously, she had written the following appraisal of a talk ("Lexiva is a great first choice PI") given by Dr. Hsu on January 12, 2004:

> "Ricky's slides are amazing. He has taken everything I have supplied him with and merged them together to make a very exciting and thought provoking presentation. He really takes everything that we disucss [sic], all of the nuisances [sic] of our product, and uses it in his lecture. GSK loves him and

have thanked me for my work with him."

This was a talk to 25 physicians and support staff for which "GSK paid, Vertex prepared speaker."

65. On October 18, 2005, Ms. Dacierno falsified her field report by inventing a conversation in which Dr. Hsu supposedly volunteered that he had a number of patients whom he had already started on a 1400/100 combination and suggested that he analyze their progress. Ms. Dacierno noted that "We are looking into the feasibility of providing him with an unrestricted educational grant" as if the idea had come from Dr. Hsu and not the Vertex HIVCOT team. In an exchange between the two on November 18, 2005, Vertex tentatively agreed to pay Dr. Hsu $7,500.

66. The study was to be a retrospective review of patients already on the off-label dose. On information and belief, there was no official protocol for this study. With the "study" already well underway, Dr. Hsu sent an email to Jill Dacierno on December 6, 2005, in which he openly solicited instructions from Vertex on what data to collect:

> "Are there any things you wanted? I'm assuming ART regimen, starting date, ending date, CD4 and viral load at various time points along with side effects. Other things? Please address the check to Ricky K. Hsu, M.D., PC."

Dacierno replied,

> "everyone says that 100 mg of RITONAVIR is much more palatable, so if the clinical data is good for a group of your patients with similar starting scenarios (NRTI's, PI naïve etc.) then it sets the stage nicely for a large clinical trial expected sometime next year."

67. On January 10, 2006, Ms. Dacierno reported that she,

> "Met with Ricky to discuss his project (1400/100 QD retrospective review). He now would like to get drug levels on the projects and submit to the Clinical Pharmacology Workshop in Lisbon."

By that time Vertex had engaged Dr. Hsu to speak "for us at my February 22nd

Advisory Board, the LA Advisory Board on March 17th and the Luminary Meeting on March 18th." In preparation for these meetings Ms. Dacierno, noted in her field report that she had,

> "Provided slides for talk (created by Tyke [White]) and walked through, again, the goals of the meeting. Ran through questions that I generated. Ricky felt very comfortable with how things were set up."

68. From that date on Vertex and GSK began using the emerging data from the Hsu "study" to convert doctors to their off label dosing strategy that their market research had shown would be so popular with the consumer. The data was presented at the "New York Thought Leader Dinner Series" – an informal version of the national advisory board meetings. In her March field report, Dacierno noted that the "majority of physicians at the NY Advisory Board of 2.22.06 had used FPV/r 1400/100 QD with great success" *but for the inexperienced or the skeptical* "Ricky's results made them more comfortable with the combination, although they would like to see interim data from the Hicks or Smith trial to prescribe this combination more frequently."

69. On June 6, 2006 GSK paid Ricky Hsu to speak at the East Bay Aids Center in San Francisco on "Reduced RTV [Ritonavir] Dosing, PPI.."

70. The next day GSK paid Hsu to speak in San Francisco. His "key points" at that roundtable were "Reduced Dose RTV [Ritonavir], Klean." (The KLEAN study of fosamprenavir-ritonavir versus lopinavir-ritonavir, each in combination with abacavir-lamivudine, for initial treatment of HIV infection over 48 weeks: a randomized non-inferiority trial. Eron J Jr; *Lancet* 2006; 368:476)

71. On the same day, GSK paid Ricky Hsu to lecture Andy Zolopa in a "peer-to-peer" meting in San Francisco. Again his key points were "Reduced Dose RTV

[Ritonavir], Klean." The two "discussed the potential to dose RTV [Ritonavir] at 100mg/day. They also discussed the preliminary results of KLEAN. Andy thinks the data on reduced dose RTV as well as KLEAN may result in better positioning of Lexiva."

72. "Ricky" became a valuable asset in the off label strategy, obediently flying the Lexiva flag. Other doctors who were not so loyal were "retrained" or received no further employment. In the process, MSL's were taught to put commercial interests first. Dr. Hsu was engaged on many lucrative speaking engagements where he addressed groups of doctors on the off-label dosing strategy and promoting the pipeline HIV drug VX 385 and, at times, tutored doctors individually in so called "peer to peer" meetings. On January 26, 2006, MSL Dacierno sent the doctor a reminder of his coast-to-coast tour dates:

> "Hello again. Just wanted to run through your scheduled talks:
>
> **NY** February, 22 (meeting starts at 5:30) Ritz Battery Park: 30 minute talk on your 1400/100 clinical and later 20 minutes dedicated to 385 overview.
>
> **LA** March 17, (meeting starts at 3:00 PST) Ritz Marina Del Ray: 30 minute talk on your 1400/100 clinical and later 20 minutes dedicated to 385 overview.
>
> **Laguna Niguel** March 18 (meeting starts at 10:00 am PST) St. Regis Monarch Beach Resort & Spa: 30 minute talk on your 1400/100 clinical and later 20 minutes dedicated to 385 overview.
>
> March 23rd **Houston**." (emphasis added)

Dacierno ended the email with a friendly invitation in case the doctor was not sure about something he was going to say "Let me know if you have any questions about the talk content. Which carrier do you like to fly?"

73. Vertex also used other ways to exert national influence with Dr. Hsu's data. On January 31, 2006, Dacierno reported that she had helped Dr. Hsu write up his results for publication.

> "worked extremely hard with Ricky ensuring that all timelines were met for the submission of his 1400/100 analysis. He did an amazing job getting patients in, at the correct times, in short order and in a new office. Samples were sent to Ed Acosta who made it a priority run and return to us as quickly as he possibly could. **Ricky got us started with an initial abstract, which Tyke pared down to a very useable and submission worthy document.**" (emphasis added)

74. Relator does not know whether the Hsu study has been accepted for publication. These activities were directly tied to promotions and bonuses including stock options and stock grants. Jill Dacierno, for example, has received several promotions because of her ability to seed fruitful "projects." She was first promoted to Medical Science Liaison Manager, later promoted to Medical Education Coordinator and most recently holds the title of Associate Director, East Coast Liaisons. This is a position which is usually held by someone with an MD, Pharm D or Ph.D.

PRE-APPROVAL MARKETING OF LEXIVA, VX 385 & VX 950

75. Prior to FDA approval, Lexiva was known as "VX 908." Despite the fact the drug did not receive approval until October 2003, GSK and Vertex were promoting Lexiva as early as April 2002. Vertex MSL's Kelly Osburn, Jill Dacierno, Chris Barnes, Mari Brill and others had speakers such as Dr. David Parks (later to produce the Parks study), Dr. Brian Boyle, Dr. Ricky Hsu, Andy Luber and Dr. Bisher Akil host fora in which the following "key points" were made: "favorable side effect profile of 908" (April 1 and April 10, 2002); "908 demographics" (August 6, 2002) and "908 both boosted and unboosted performed as expected. (February 25, 2003)" In talks on April 10, and May

14, 2003, Drs Colwell and Haubrick hosted roundtables at which they presented Brian Boyle's Lexiva-friendly PI Comparison slide deck.

76. The field reports are replete with examples of the pre-approval marketing of the VX 385 and VX 950; and such off-label promotional activities were explicitly written into their Annual goals. For example, in the case of VX 385 each MSL was required to include the names of three doctors whom they had provided with information on VX 385. The form itself reads "Provide three KOLs with requested information on 385 for inclusion in new product updates." (emphasis added) Somehow MSL's were to ensure that at least three doctors "requested" this information.

RECENT SHIFT IN VERTEX STRATEGY

77. In the fall of 2006, Vertex management issued a blanket order to all MSL's that they should no longer make notes of any calls or interactions with HIV physicians; that henceforth, the MSL's were to switch focus to Hepatitis C physicians, who at that point made up just 10% of the "targets." In effect, the MSL's were instructed to abandon sales efforts with HIV doctors and use their influence on HCV doctors to conduct market development activities for VX 950 (Telapravir). These activities included building relationships with thought leaders and high prescribers in HCV and seeking physicians to conduct "Disease State Research" which would help emphasize the growing need for new therapies for HCV. The pre-approval marketing of VX 950 has been going on since 2005. For example, in an email of September 29, 2005, Jill Dacierno wrote to a Dr. Jules Levin to inform him of the potency of the new pipeline drug VX 950: "Just wanted to get your personal take on the HCV protease inhibitor data that was presented at the liver meeting. Obviously all are in early stages…..Best, Jill." The doctor

responded that "Hi Jill. I'm excited about VX 950. I'd like to meet with the right Vertex people about development plans."

78. While the pre-approval marketing has been going on for some time, the Vertex recent strategy shift to focus exclusively on HCV and VX 950 is a watershed for the company and reflects sentiment at Vertex that VX 950 will be a "blockbuster." Hence Vertex has retained exclusive rights to exploit VX 950 in North America and has announced plans to amass its own sales force.

DANGERS

79. Vertex MSL's were instructed to make sure that all meetings with physicians should include the latest favorable data on Agenerase and later Lexiva. This information was often later at HIV/AIDS conferences. For example, MSL's were required to convey the message that Agenerase was particularly effective when taken in combination with Kaletra. This type of promotion went on for several years before a trial conducted by the AIDS Clinical Trials Group ("ACTG") (ACTG Study 5143) had to be stopped when it was observed that the two drugs were *antipathetic* and their combination caused a drop in blood levels of *both* Lopinavir (one of the two constituents of Kaletra) and Agenerase. The package inserts of both Lexiva and Kaletra were amended to reflect this information. The current Lexiva package inserts states "an increased rate of adverse events has been observed with administration of these two medications [Kaletra and Lexiva]." However, the reduced-dose Ritonavir strategy poses even greater dangers for the patient.

80. One of the challenges that makes HIV so hard to treat is the ability of the virus to mutate and multiply. In many cases, mutations are not susceptible to the

patient's current regimen and the efficacy of the regimen is compromised. This usually corresponds to loss of virologic suppression and the patient's physician selects a new regimen which is more likely to combat the mutated virus. Protease inhibitors are frequently boosted with Ritonavir to ensure adequate drug levels and hence efficacy. Dosing Lexiva with less than the indicated amount of Ritonavir may lead to inadequate drug levels leading to a loss of efficacy. The patient may also develop drug resistance which may not be overcome by another currently approved antiviral.

81. It has been shown in long-term studies that when patients fail to thrive on a combination of Lexiva 1400 mg combined with 200 mg of Ritonavir, they *should* be able to sequence to another protease inhibitor in place of Lexiva. A resistance analysis of patients from the SOLO study, a large scale registrational trial of Lexiva taken as 1400 mg with 200 mg of Ritonavir (once a day), showed no emergence of Protease Inhibitor resistance upon virologic failure. ("Long-term (120-week) antiviral efficacy and tolerability of fosamprenavir/ritonavir once daily in therapy-naive patients with HIV-1 infection: An uncontrolled, open-label, single-arm follow-on study." Gathe JC Jr, Wood R, Sanne I, et al. Clin Therap. 2006;28:745-754.) However, 13% of patients failing the Lexiva combination developed mutations to the reverse transcriptase, meaning that they would be less likely to be susceptible to certain nucleoside reverse transcriptase inhibitors.

82. By contrast, a similar analysis to *unboosted* Lexiva from the NEAT study showed significant Protease and Reverse Transcriptase resistance upon virologic failure. ("A 48-week open-label study to compare the antiviral efficacy and safety of GW433908 versus nelfinavir in antiretroviral therapy-naive HIV-1-infected patients." Rodrigues-

French A, Boghossian J, Gray F, et al. *J Acquir Immune Defic Syndr.* 2003;35:22-32.) For example, 28% of patients failing Lexiva failed with primary or secondary resistance mutations and 55% of patients failing Lexiva failed with resistance to reverse transcriptase inhibitors.

83. This underscores the importance of the boosting agent. Unless long term studies, which include resistance analysis, are performed for patients taking a lower dose of Ritonavir, it is unknown what effect Lexiva therapy in the reduced-Ritonavir dose will have on the long term efficacy of the regimen and activity of subsequently administered protease inhibitors. In other words, the off-label prescription of Lexiva with the reduced supplement of Ritonavir under 200 mg can lead to loss of viral suppression and may deprive the patient of long-term alternatives to certain protease inhibitors *and* reverse transcriptase inhibitors. This is known as developing cross-resistance and the consequences can be fatal.

DAMAGES

84. The United States National Institutes of Health has estimated that there are as many as 950,000 individuals living with HIV in the United States in 2006. Protease inhibitors are just one of four classes of drugs used to treat HIV infection. Sales of HIV PI's in the United States exceeded $2 billion in 2006 (excluding Ritonavir).

85. Agenerase went on sale in the United States in May of 1999, that year generating $56 million in sales (assuming a dollar/pound exchange of 2:1). In 2000 sales improved 52% reaching $92 million, but fell by 21% in 2001 to $76 million. In 2002, the year before Lexiva's FDA approval, Agenerase generated just $62 million in sales, down 15% on the previous year. In 2003 sales of Agenerase dropped a further 33% to $38

million. Of these sales, Relator estimates that 30% resulted from the off-label push to have Lexiva prescribed in conjunction with Kaletra. This suggests that of overall sales, approximately $106 million was the result of Defendants unlawful activities in respect of Agenerase.

86. At the end of 2003 Lexiva entered the market. According to GSK annual reports, in 2004 Lexiva together with Agenerase generated $92 million in turnover. (While the GSK annual report conflates the sales of Lexiva/Agenerase, the Vertex annual report comments that "Lexiva/Telzir has replaced Agenerase in worldwide markets." Vertex Annual Report 2006 p. 12.) *In 2005, sales improved 50% to reach $140 million.* When the sales numbers were known for 2005, Tyke White credited the "low dose strategy" as one of the main factors driving sales. Most recently, Lexiva sales rose only modestly reaching $148 million in 2006 making it the third most successful HV PI in the United States with 11 % of the market (excluding Ritonavir). The two most successful HIV PI's are Bristol-Myers Squibb's Reyataz and Abbott Laboratories' Kaletra (Lopinavir with Ritonavir).

87. Vertex's Royalties consist of Lexiva sales and a small amount of sales for Agenerase. From 2004 to 2005, sales of Lexiva rose 50%, whereas royalties from those sales rose 90% from $17.3 million to $32.8 million. In 2006, Lexiva sales rose at a modest 6%, whereas royalty revenues from those sales were $42.2 million, up 26% from 2005. The disparity suggests that GSK pays royalties based on a "stepped scale", rather than as a simple percentage, thus Vertex enjoys a disproportionate benefit from any growth in sales of Lexiva. Despite the statement in their 2006 annual report that "We have no experience as a company in sales and marketing" and "GlaxoSmithKline directs

the majority of the marketing and sales efforts and the positioning of Lexiva/Telzir in the overall market, and we have lttile control over the dircetion or success of those efforts." It appears, Vertex is rewarded disproportionately for sales growth and is incentivized as if it does, in fact, bear significant responsibility for sales and marketing.

88. The number of patients who might take Lexiva without any Ritonavir booster is very small because (i) only newly-diagnosed HIV patients would be eligible as "therapy naïve;" and (ii) the Department of Health and Human Services (DHHS) and the International AIDS Society (IAS) have both produced guidelines recommending a Ritonavir-boosted PI as the preferred *first* line regimen for any patient *initiating* PI based therapy. Therefore, the vast majority of any Lexiva patients will be receiving it with some level of Ritonavir and all prescriptions which require less than the full 200 mg boost, are "off label." Katy Tighe, sales rep at GSK, told Relator that of all the precriptions written to Lexiva, approximately 60% were written for the off-label reduced-Ritonavir dose. This equates to approximately $228 million of Lexiva's overall sales.

COUNT ONE

[False and/or Fraudulent Claims, 31 U.S.C. § 3729 (a)(1)]

89. Relator restates and realleges the allegations in paragraphs 1 through 88 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

90. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

91. Through the above-described acts and omissions, and from at least on or before October 2000 to the present, the Defendants knowingly caused to be presented for

for payment and approval false and/or fraudulent claims to officers of the United States Government, in that they caused to be presented claims to obtain reimbursement for the drugs when the Defendants knew such items were not eligible for reimbursement or not eligible in part. Prescriptions for these drugs would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity and resulted in claims which failed to disclose the material violations of the AKA and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1).

92. Federal Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for the drugs that should not have been paid or approved.

93. The Defendants, through the means described above, deliberately and intentionally concealed the false and fraudulent nature of the claims from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

94. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for the drugs had they known the truth.

95. By reason of the above-described presentment of false and fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT TWO

[False Records and Statements, 31 U.S.C. § 3729 (a)(2)]

96. Relator restates and realleges the allegations in paragraphs 1 through 95 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

97. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

98. Through the above-described acts and omissions, and from on or before at least October 2000 to the present, the Defendants knowingly made and used, and caused to be made and used, false records and statements for the purpose of having false and fraudulent claims for the drugs paid and approved by Federal Health Care Program officials, their contractors, carriers, intermediaries and agents. Such prescriptions would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(2).

99. By reason of the above-described presentment of false records and statements, the United States has suffered significant losses in an amount to be determined.

COUNT THREE

[Conspiracy to Defraud, 31 U.S.C. § 3729 (a)(3)]

100. Relator restates and realleges the allegations in paragraphs 1 through 99 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

101. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

102. Through the above-described acts and omissions, and from on or before at least October 2000 to the present, the Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal and state governments by having false and fraudulent claims for the drugs paid and approved by Federal Health Care Program officials, their contractors, carriers, intermediaries and agents. Such prescriptions would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)-(2).

103. By reason of the above-described unlawful conspiracy, the United States has suffered significant losses in an amount to be determined.

COUNT FOUR

[False Statements to Conceal Obligations, 31 U.S.C. § 3729(a)(7)]

104. Relator restates and realleges the allegations in paragraphs 1 through 103 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

105. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

106. Through the above-described acts and omissions, the Defendants knowingly made and used, and/or caused to be made and used, false records and statements regarding the drugs in order to conceal, avoid and/or decrease the Defendants' obligations to pay or transmit rebate monies or to offer certain prices to Government Health Care Programs to the United States. In addition, these claims were monetarily

excessive because they were improperly inflated by Defendants' illegal marketing and promotional activities. Claims to Government Health Care Programs as described above were false or fraudulent and the statements and records were false because they were monetarily excessive.

107. By reason of the above-described false records and statements, the United States has suffered significant losses in an amount to be determined.

COUNT FIVE

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(1)

108. Relator restates and realleges the allegations in paragraphs 1 through 107 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

109. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> 33. Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

110. Defendants knowingly presented or caused to be presented to the

California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov't Code § 12651(a)(1).

111. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIX

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(2)

112. Relator restates and realleges the allegations in paragraphs 1 through 111 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

113. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state… for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

114. Defendants knowingly made, used and/or caused to be made or used false records and statements to get false and fraudulent claims paid and approved by the

California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(2).

115. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVEN

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(3)

116. Relator restates and realleges the allegations in paragraphs 1 through 115 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

117. The California False Claims Act, Cal. Gov't Code § 12651(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (3) Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . . .

118. Defendants conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

119. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHT

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(7)

120. Relator restates and realleges the allegations in paragraphs 1 through 119 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

121. The California False Claims Act, Cal. Gov't Code § 12651(a)(7), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state . . . .

122. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Cal. Gov't Code § 12651(a)(7).

123. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(1)

124. Relator restates and realleges the allegations in paragraphs 1 through 123 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

125. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

(a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

126. Defendants knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

127. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(2)

128. Relator restates and realleges the allegations in paragraphs 1 through 127 above as if each were stated herein in their entirety and said allegations are incorporated

herein by reference.

129. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

> (a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

130. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

131. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ELEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(3)

132. Relator restates and realleges the allegations in paragraphs 1 through 131 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

133. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(3), specifically provides, in part, that any person who:

(a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

134. Defendants conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

135. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWELVE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(7)

136. Relator restates and realleges the allegations in paragraphs 1 through 135 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

137. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(7), specifically provides, in part, that any person who:

(a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

138. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

139. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(1)

140. Relator restates and realleges the allegations in paragraphs 1 through 139 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

141. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

142. Defendants knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which

failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308.14(a)(1).

143. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FOURTEEN
VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT
D.C. Code § 2-308.14(a)(2)

144. Relator restates and realleges the allegations in paragraphs 1 through 143 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

145. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

146. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

147. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(3)

148. Relator restates and realleges the allegations in paragraphs 1 through 147 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

149. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

150. Defendants conspired to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

151. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(7)

152. Relator restates and realleges the allegations in paragraphs 1 through 151 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

153. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(7), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government;

154. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of D.C. Code § 2-308.14(a)(7).

155. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(a)

156. Relator restates and realleges the allegations in paragraphs 1 through 155 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

157. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), specifically provides, in part, that any person who:

> (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval; …is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

158. Defendants knowingly presented or caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Fla. Stat. § 68.082(2)(a).

159. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTEEN
VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(b)

160. Relator restates and realleges the allegations in paragraphs 1 through 159 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

161. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), specifically provides, in part, that any person who:

> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; … is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

162. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Florida, in violation of Fla. Stat. § 68.082(2)(b).

163. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(c)

164. Relator restates and realleges the allegations in paragraphs 1 through 163 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

165. The Florida False Claims Act, Fla. Stat. § 68.082(2)(c), specifically provides, in part, that any person who:

> (c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and

for treble the amount of damages the agency sustains because of the act or omission of that person.

166. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Federal/Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

167. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(g)

168. Relator restates and realleges the allegations in paragraphs 1 through 167 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

169. The Florida False Claims Act, Fla. Stat. § 68.082(2)(g), specifically provides, in part, that any person who:

> (g) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

170. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay

or transmit money to the state, in violation of Fla. Stat. § 680.82(2)(g).

171. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-ONE

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

172. Relator restates and realleges the allegations contained in Paragraphs 1 through 171 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

173. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq*., specifically provides, in part at 49-4-168.1, that:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
> (4) Has possession, custody, or control of property or money used, or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt…or
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia,
> shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

174. The Defendants knowingly presented or caused to be presented false or

fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Programs. Prescriptions for the purposes of off-label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia FCA, 49-4-168.1(a)(1)-(2).

175. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive. Prescriptions for the purposes of off-label uses cost more than comparative drugs with the same or superior efficacy.

176. In particular, these claims were also false or fraudulent and statements and records were false because the cost to the Government Healthcare Programs was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

177. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating 49-4-168.1(a)(1)-(2), Defendants' conduct violated 49-4-168.1(a)(4) and (7).

178. Defendants knowingly conspired to defraud the State of Georgia causing increased sales through unlawful promotion and kickbacks in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to write unnecessary prescriptions. Said actions constitute violations of 49-4-168.1(a)(3).

179. Defendants knowingly conspired to violate the Georgia FCA by causing

false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of 49-4-168.1(a)(3).

180. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotional activities. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 49-4-168.1(a)(3).

181. Defendants knowingly presented or caused to be presented to the Georgia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 49-4-168.1(a)(1)-(4) and (7).

182. The State of Georgia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Georgia, because of these acts by the Defendants.

COUNT TWENTY-TWO

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(1)

183. Relator restates and realleges the allegations in paragraphs 1 through 182

above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

184. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

185. Defendants knowingly presented or caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Haw. Rev. Stat. § 661-21(a)(1).

186. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-THREE
VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(2)

187. Relator restates and realleges the allegations in paragraphs 1 through 186 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

188. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(2), specifically provides, in part, that any person who:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

189. Defendants knowingly made, used and caused to be made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

190. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FOUR

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(3)

191. Relator restates and realleges the allegations in paragraphs 1 through 190 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

192. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3), specifically provides, in part, that any person who:

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

193. Defendants conspired to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

194. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FIVE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(7)

195. Relator restates and realleges the allegations in paragraphs 1 through 194 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

196. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(7), specifically provides, in part, that any person who:

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

197. Defendants knowingly made, used or caused to be made or used a false

record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Haw. Rev. Stat. § 661-21(a)(7).

198. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SIX

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWERREWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3 (a)(1)

199. Relator restates and realleges the allegations in paragraphs 1 through 198 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

200. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

201. Defendants knowingly caused to be presented to the Illinois Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

202. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SEVEN
VIOLATIONS OF THE ILLINOIS
WHISTLEBLOWER REWARD AND PROTECTION ACT
740 Ill. Comp. Stat. § 175/3(a)(2)

203. Relator restates and realleges the allegations in paragraphs 1 through 202 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

204. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

205. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

206. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-EIGHT

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(3)

207. Relator restates and realleges the allegations in paragraphs 1 through 206 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

208. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(3), specifically provides, in part, that any person who:

> (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

209. Defendants conspired to defraud the State of Illinois by getting false and fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

210. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-NINE

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(7)

211. Relator restates and realleges the allegations in paragraphs 1 through 210 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

212. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(7), specifically provides, in part, that any person who:

> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

213. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

214. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5

215. Relator restates and realleges the allegations in paragraphs 1 through 214 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

216. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount

of damages that the state sustains because of the act of that person [including]:

> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claims from the state;...
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described above; or
> (8) causes or induces another person to perform an act described above.

217. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the Indiana Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired to defraud the state Medicaid program, and caused others to violate the Indiana Act, all in violation of IC 5-11-5.5-2.

218. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-ONE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.3A

219. Relator restates and realleges the allegations in paragraphs 1 through 218 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

220. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, specifically provides, in part, that: "No person shall knowingly present or cause to be presented a false or fraudulent

claim".

221. Defendants knowingly presented or caused to be presented to the Louisiana Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 46 La. Rev. Stat. c. 3 § 438.3A.

222. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-TWO
VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3B

223. Relator restates and realleges the allegations in paragraphs 1 through 222 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

224. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, specifically provides, in part, that:

> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

225. Defendants knowingly engaged in misrepresentation and made, used and caused to be made and used, false records and statements to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Illinois, in violation of 46 La. Rev. Stat. c. 3 § 438.3B.

226. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-THREE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.3C

227. Relator restates and realleges the allegations in paragraphs 1 through 226 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

228. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3C, specifically provides, in part, that:

> No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

229. Defendants conspired to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid, in violation of 46 La. Rev. Stat. c. 3 § 438.3C.

230. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FOUR

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW 46 La. Rev. Stat. c. 3 § 438.2A(1)

231. Relator restates and realleges the allegations in paragraphs 1 through 230 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

232. Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.2A(1), specifically provides that:

No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or … payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following . ..

(1) In return for referring an individual to a health care provider, …for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

233. In addition, the Louisiana FCA, supra, section 438.3 provides that:

"No person shall knowingly present of cause to be presented a false or fraudulent claim…shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds…shall conspire to defraud, or attempt to defraud, the medical assistance programs… ."

234. Furthermore, the Louisiana FCA, supra, section 438.4 provides that:

"No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility … to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive."

235. Defendants solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat. c. 3 § 438.2A(1).

236. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FIVE

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(1)

237. Relator restates and realleges the allegations in paragraphs 1 through 236 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

238. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

239. Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

240. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SIX
VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(2)

241. Relator restates and realleges the allegations in paragraphs 1 through 240

above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

242. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

243. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of claim by the Commonwealth of Massachusetts, in violation of Mass. Gen. Laws Ch. 12, § 5B(2).

244. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SEVEN

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(3)

245. Relator restates and realleges the allegations in paragraphs 1 through 244 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

246. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(3), specifically provides, in part, that any person who:

> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> . . .
>
> shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

247. Defendants conspired to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

248. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-EIGHT

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(8)

249. Relator restates and realleges the allegations in paragraphs 1 through 248 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

250. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(8), specifically provides, in part, that any person who:

> (8) knowingly makes, uses, or causes to be made or used, a false record or

statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

251. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Mass. Gen. Laws Ch. 12, § 5B(8).

252. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-NINE

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MI ST Ch. 400

253. Relator restates and realleges the allegations in paragraphs 1 through 252 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

254. The Michigan Medicaid False Claims Act, MI ST Ch. 400, provides, *inter alia*: as follows:

(1) In section 400.603, that "A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits… [or] for use in determining rights to a Medicaid benefit." It further provides that "A person, having knowledge of the occurrence of an event affecting

…[the] initial or continued right of any other person on whose behalf he has applied…shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled."

(2) In section 400.606, that "A person shall not enter into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim… ."

(3) In section 400.607, that "A person shall not make or present or cause to be made or presented to an employee or officer [of the state] a claim…upon or against the state, knowing the claim to be false… ." and that " A person shall not make or present or cause to be made or presented a claim …which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary … ."

(4) In section 400.604, that a person is prohibited from soliciting, offering, making or receiving a kickback or bribe or rebate of any kind.

255. Under section 400.612, "A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person".

256. Defendants have violated these provisions of the Michigan FCA and caused damage to the State of Michigan.

COUNT FORTY

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(a)

257. Relator restates and realleges the allegations in paragraphs 1 through 256 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

258. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> (a) Knowingly presents or causes to be presented a false claim for payment or approval.

259. Defendants knowingly presented or caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Nev. Rev. Stat. § 357.040(1)(a).

260. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-ONE
VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(b)

261. Relator restates and realleges the allegations in paragraphs 1 through 260

above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

262. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

263. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

264. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-TWO

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(c)

265. Relator restates and realleges the allegations in paragraphs 1 through 264 above as if each were stated herein in their entirety and said allegations are incorporated

herein by reference.

266. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(c), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (c) Conspires to defraud by obtaining allowance or payment of a false claim.

267. Defendants conspired to defraud the State of Nevada by obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

268. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-THREE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(g)

269. Relator restates and realleges the allegations in paragraphs 1 through 268 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

270. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(g), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

. . .

(g) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state....

271. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Nev. Rev. Stat. 357.040(1)(g).

272. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FOUR

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b *et seq.*

273. Relator restates and realleges the allegations in paragraphs 1 through 272 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

274. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq*. (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount

of damages that the state sustains because of the act if that person:

> (a) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim;
>
> (b) makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> (c) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]
>
> (e) makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false...."

275. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Hampshire Medicaid program false and/or fraudulent claims for payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.H. RSA § 167:61-b I. (a)-(c) and (e).

276. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FIVE

VIOLATIONS OF THE NEW MEXICO FCA N.M. LEGIS 49 (2004) CHAPTER 4

277. Relator restates and realleges the allegations in paragraphs 1 through 276 above as if each were stated herein in their entirety and said allegations are incorporated

herein by reference.

278. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;

4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

4C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

4D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]

4E. makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false…."

279. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Mexico Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations

of the AKA and other laws; they knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.M. Legis 49 (2004) Chapter 4A-E.

280. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-SIX

VIOLATIONS OF THE NEW YORK STATE FCA: 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII, §189 (a)(1),(2) and (7)

281. Relator restates and realleges the allegations contained in Paragraphs 1 to 280 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

282. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Program. Prescriptions for the purposes of off-label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to Art. XIII, §189(a)(1).

283. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of Art. XIII, §189 (a)(1)-(2). Prescriptions for the purposes of off-label uses cost more than comparative drugs with the same or superior efficacy.

284. In particular, these claims were also false or fraudulent and statements and records were false because the cost to Government Healthcare Programs was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

285. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating Art. XIII, §189(a)(1)-(2), Defendants' conduct violated Art. XIII, §189 (a)(7).

COUNT FORTY-SEVEN

CONSPIRACY TO DEFRAUD: NEW YORK FCA, 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII §189 (a)(3)

286. Relator restates and realleges the allegations contained in Paragraphs 1-285 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

287. Defendants knowingly conspired to defraud the State of New York causing increased sales through unlawful promotion in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions. Said actions constitute violations of Art.13, Section 189(a)(3).

288. Defendants knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives. Said claims were also

monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of Art. XIII, Section 189(a)(3).

289. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotional activities. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of Art XIII, Section 189(a)(3).

COUNT FORTY-EIGHT

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(A)

290. Relator restates and realleges the allegations in paragraphs 1 through 289 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

291. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically provides, in part, that any person who:

> (A) Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

292. Defendants knowingly presented or caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

293. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-NINE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(B)

294. Relator restates and realleges the allegations in paragraphs 1 through 293 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

295. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), specifically provides, in part, that any person who:

> (B) Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

296. Defendants made, used and caused to be made and used, records and statements to get false and fraudulent claims under the Medicaid program paid and

approved by the State of Tennessee knowing such records and statements were false, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

297. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(C)

298. Relator restates and realleges the allegations in paragraphs 1 through 297 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

299. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C), specifically provides, in part, that any person who:

> (C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

300. Defendants conspired to defraud the State of Tennessee by getting claims allowed and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(C).

301. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-ONE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(D)

302. Relator restates and realleges the allegations in paragraphs 1 through 301 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

303. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(D), specifically provides, in part, that any person who:

> (D) Makes, uses, or causes to be made or sued, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program knowing such record or statement is false;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

304. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

305. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-TWO

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(1)-(2)

306. Relator restates and realleges the allegations in paragraphs 1 through 305 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

307. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), specifically provides, in part, that a person commits an unlawful act if the person:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

(A) on an application for a contract, benefit, or payment under the Medicaid program; or

(B) that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program.

308. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(2)(B), specifically provides, in part, that a person commits an unlawful act if the person:

(2) knowingly or intentionally conceals or fails to disclose an event: (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized… ."

309. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, claims which failed to disclose the material violations of the

AKA and other laws, in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

310. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT FIFTY-THREE

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(4)(B)

311. Relator restates and realleges the allegations in paragraphs 1 through 310 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

312. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> . . .
>
> (B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

313. Defendants by knowingly and intentionally causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and provider agreements pertaining to the Medicaid program, are in violation of Tex. Hum. Res. Code § 36.002(4)(B).

314. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FOUR

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW Tex. Hum. Res. Code § 36.002(5)

315. Relator restates and realleges the allegations in paragraphs 1 through 314 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

316. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

> (5) except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program . . . .

317. Defendants knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §36.002(5).

318. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FIVE

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(9)

319. Relator restates and realleges the allegations in paragraphs 1 through 318 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

320. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

> (9) knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . .

321. Defendants knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §36.002(9).

322. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT FIFTY-SIX

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(1)

323. Relator restates and realleges the allegations in paragraphs 1 through 322 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

324. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), specifically provides, in part, that any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

325. Defendants knowingly presented or caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

326. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-SEVEN

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(2)

327. Relator restates and realleges the allegations in paragraphs 1 through 326 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

328. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), specifically provides, in part, that any person who:

> 2. Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the

Commonwealth;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

329. Defendants knowingly made, used and caused to made and used, false records and statements to get false and fraudulent claims paid and approved by the Commonwealth of Virginia, in violation of Va. Code Ann. §8.01-216.3(A)(2).

330. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-EIGHT

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)(3)

331. Relator restates and realleges the allegations in paragraphs 1 through 330 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

332. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(3), specifically provides, in part, that any person who:

3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by

the Commonwealth.

333. Defendants conspired to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann. § 8.01-216.3(A)(3).

334. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-NINE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(7)

335. Relator restates and realleges the allegations in paragraphs 1 through 334 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

336. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7), specifically provides, in part, that any person who:

> knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

337. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay

PRAYERS FOR RELIEF

WHEREFORE, Relator, acting on behalf of and in the name of the United States of America and the State Plaintiffs, and on her own behalf, demand and pray that judgment be entered as follows against the Defendants under the Federal FCA Counts and under supplemental State FCA Counts as follows:

(a) In favor of the United States against the Defendants jointly and severally for treble the amount of damages to Government Health Care Programs from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

(c) In favor of the Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;

(d) For all costs of the Federal FCA civil action;

(e) In favor of the Relator and the United States for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relator and the named State Plaintiffs against Defendants jointly and severally in an amount equal to three times the amount of damages that California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, New York, Tennessee, and Virginia have

sustained, respectively, as a result of the Defendants' actions, as well as the statutory maximum civil penalty against the Defendants for each violation of each State's FCA;

(g) In favor of the Relator and the Plaintiff State of Texas against Defendants jointly and severally in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

(h) In favor of the Relator and the State of Michigan against the Defendants jointly and severally for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of the Defendants' actions, plus damages equal to three times such loss;

(i) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to the State FCAs as follows: Cal. Gov't Code 12652(g); Del. Code Ann. Tit. 6, § 1205; D.C. Code § 2-308.14(f); Fla. Stat. § 68.085; Official Code of Georgia Annotated, 49-4-168; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat. § 175/4(d); IC 5-11-5.5; 46 La. Rev. Stat. c. 3, § 437.1 et seq.; Mass. Gen. Laws Ch. 12, § 5F; Nev. Rev. Stat. §§ 357.210, 357.220, MI ST Ch. 400; N.H. RSA §§ 167:61-b; N.M. Legis 49 (2004); Chapter 4, NY laws 58, s. 39, Art. XIII, §189; Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code § 36.110, and Va. Code Ann. § 8.01-216.7;

(j) In favor of the Relator for all costs and expenses associated with the supplemental State claims, including attorney's fees and costs; and

(k) In favor of the State Plaintiffs and the Relator for all such other relief as the Court deems just and proper.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Dated: September , 2007

Respectfully submitted,

Timothy J. McInnis
[TM7151]
Law Office of Timothy J. McInnis
521 Fifth Ave, Suite 1700
New York, NY 10175-0038
Tel: (212) 292-4573
Fax: (212) 292-4574

Local Counsel

Robert M. Thomas, Jr.
(Mass. BBO #645600)
Rory Delaney
(Mass. BBO #655666)
THOMAS & ASSOCIATES
Federal Reserve Building
600 Atlantic Avenue, 12th Floor
Boston, MA 02210
(617) 371-1072
Fax: (617) 371-1037

Suzanne E. Durrell
(Mass. BBO #139280)
DURRELL LAW OFFICE
180 Williams Avenue
Milton, Massachusetts 02186
(617) 333-9681
Fax: (617) 333-0014